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# Exhibit 7

## **CONCEPT TEMPLATE**

<b>Project Title:</b>	<b>Low Profile Shaft</b>	<b>Project # 1203</b>
<b>Contact:</b>	Bob Ainsworth	
<b>Project Core Team:</b>	Bob Ainsworth Dave Jacobson Dave Young Ted Slater Jeong Lee Ziyun Chen Wanda Dziechciarz Edward McCarroll Mike Buchin Dan Cox Mfg. Eng. (TBD)	Project Leader
<b>Date:</b>	Concept Template:	January 24, 1994
	Update Presentation:	January 28, 1994
<b>Type of Innovation:</b>	Shaft Technology	

## **PROJECT OBJECTIVES**

1. **Short Term Objective:** Complete specific deliverables for the prioritized dilatation catheter projects that contribute to the projects' goals and objectives by the application of core shaft technologies.
2. **Intermediate Term Objective:** Develop optimum shaft assemblies in elliptical and coaxial geometries that provide leading edge shaft performance and reduced COPS for the OTW and RX market segments by the application of core shaft technologies.

Complete optimum shaft components and shaft assemblies by Q2 '95.

Core Shaft Technologies include: 1. shaft materials and components; 2. shaft testing, analysis and design; and 3. shaft assembly processes.

Key shaft performance characteristics: track, push, shaft size and guide wire movement.

COPS benchmark is the manufacturing costs of the New .014 Platform products.

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## **SYNERGY with STRATEGIC ACS OBJECTIVES**

### **Dominate POBA**

Best possible .014 OTW shafts  
Best possible .014 RX shafts

### **Outpatient PTCA/AMI (direct PTCA)**

Target smaller guide use

### **Improve performance in CTO**

Distal tip design

### **Lower COPS**

## **MARKET INFORMATION**

The Low Profile Shaft project supplies shaft technologies for the .014 platform project and the OTW and RX products that result and for the "next generation" of OTW and RX products that follow those developed in the .014 platform project.

### **Estimated Market Size**

OTW Domestic  
OTW International  
RX Domestic  
RX International

### **Market Window**

The shaft technology contributions to the .014 Platform project, the VHP catheter project and Primaflow project are timed to support the timelines of those projects. With concept reviews planned for Q1 or Q2 of 1994, the shaft projects are planned to be completed by that time (except for process and/or vendor qualification requirements). Shaft engineers are working closely with the dilatation catheter development product engineers so that shifts in product development timelines can be accommodated.

The shaft optimization portion of the Low Profile Shaft project is planned to be completed by Q2 1995. This timing will provide completed shaft technologies to be used for OTW and RX products that are planned for market release by Q4 1996 or Q1 1997.

### **Target Customers**

The target customers for the Low Profile Shaft project are **ACS product development** and **ACS manufacturing**. This project is specifically targeted for the current and future dilatation catheter product development projects and dilatation catheter manufacturing

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## **CUSTOMER NEEDS ANALYSIS**

The needs for ACS dilatation catheter development are in terms of performance features offered by the shaft components and technology features that facilitate the product development process.

The catheter performance needs defined in the dilatation catheter House Of Quality that are related to catheter shafts are:

1. **Catheter Performance**

- a) slide through tortuous artery without resistance (Track)
- b) transmit push from back end to distal tip (Push)
- c) smooth movement between catheter and guide wire (Guidewire Movement)
- d) improved cross/recross (distal shaft tip design)
- e) good inflation and deflation times
- f) catheter shaft doesn't kink during use
- g) no separation of catheter shaft segments

2. **Downsizing Systems**
  - a) improved visualization
  - b) two balloon catheters in a guide
  - c) smaller guiding catheters

Technology features that facilitate product development include:

1. **"Off the Shelf" shaft technology** (technology complete when needed)
  - a) shaft materials and components fully characterized
  - b) shaft component fabrication processes qualified where appropriate
  - c) shaft material/component vendors qualified
  - d) shaft assembly processes defined and qualified where appropriate

The needs of ACS dilatation catheter manufacturing from shaft technology include:

1. Qualified sources for shaft materials and/or components
  2. Robust shaft component manufacturing and shaft assembly processes
  3. Qualified shaft component manufacturing and shaft assembly processes
  4. Lower Cost shaft assemblies
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## **TECHNOLOGY** (description of project)

### **Project Goals**

**Short Term Goals:** Deliverables for prioritized dilatation catheter projects.

1. Complete distal soft tip development and recommendation by 3/31/94 for the .014 Platform development project.
2. Complete the inner member development and recommendation for the coaxial OTW .014 platform project by 3/31/94.
3. Develop lower cost shaft components as alternatives to Elastinite for the .014 Platform project and deliver to the team by 3/31/94.
4. Complete analysis of elliptical vs. coaxial shaft designs for .014 platform project by 3/31/94, to include theoretical inflation/deflation times and theoretical shaft stiffnesses that correlate to push and tract performance.
5. Complete testing and analysis of the VHP catheter shaft (dual lumen version) and provide recommendation to the VHP team by 1/31/94.
6. Complete Primaflow shaft failure (collapse under balloon) analysis and recommendation by 2/28/94.

## **Project Goals**

**Intermediate Term Goals:** Develop optimum elliptical and coaxial catheter shaft assemblies.

The shaft assemblies will demonstrate:

1. Better or equal shaft performance when compared to leading front line catheters in:
    - a) Track
    - b) Push
    - c) Wire Movement
    - d) Cross (as affected by the distal shaft tip).
  2. Shaft profile such that performance is better or equal to leading catheters:
    - a) in proximal flow when used in a 6F guiding catheter
    - b) when catheter and 2 wires are used in a 7F guide
    - c) when two catheters are used in an 8F guide.
  3. Deflation times of 12 seconds or less.
  4. Shaft does not kink during normal use.
  5. Lower COPS than shafts of .014 platform project products.
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## **DESCRIPTION OF SHAFT TECHNOLOGIES**

### **Project Plan Overview**

This project will consist of applying three core shaft technologies to achieve the short term and intermediate term goals. The three technologies are 1) shaft materials and components, 2) shaft testing, analysis and design, and 3) shaft assembly processes.

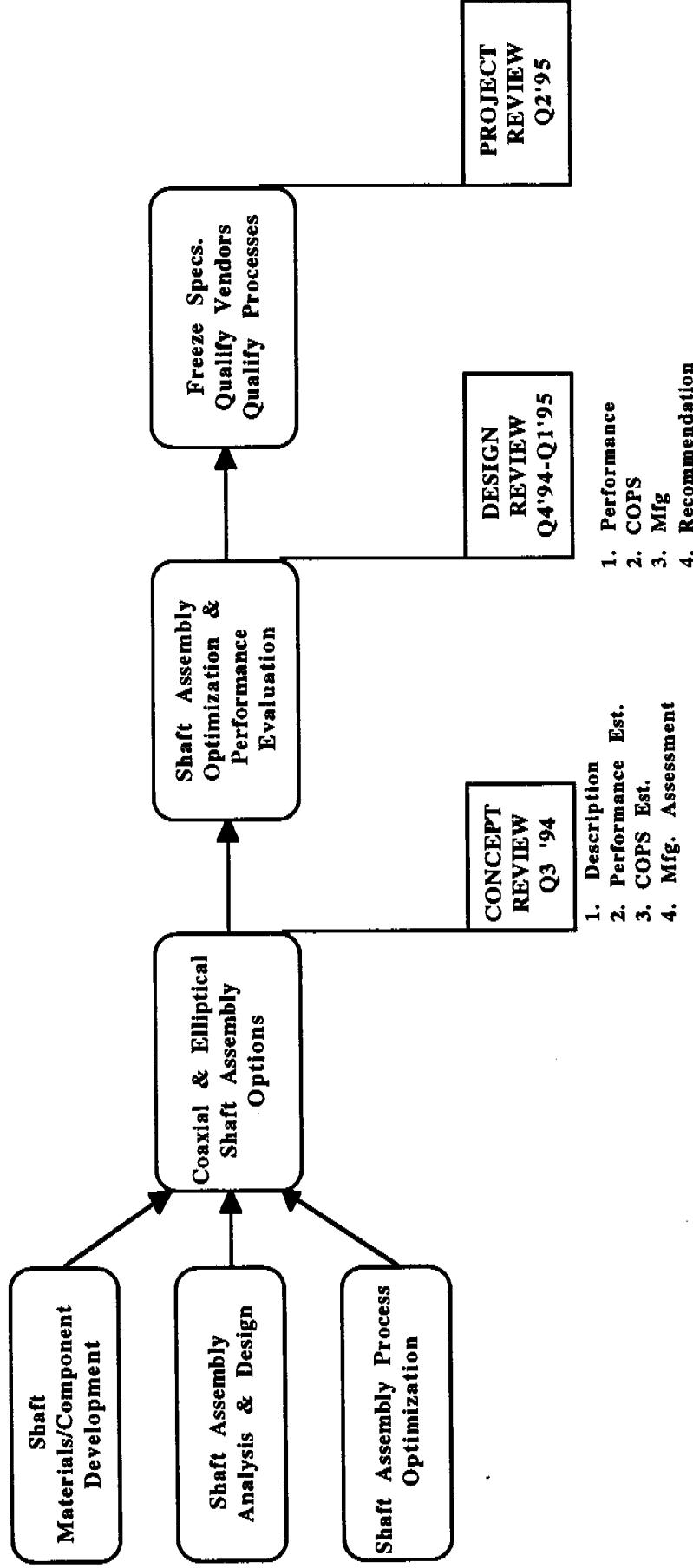
The short term project goals will be accomplished by applying the first two technologies.

The intermediate term project will consist of applying the three technologies to create shaft assemblies that will be used as vehicles to assess the shaft contribution to catheter performance, with respect to the project goals. Several candidate assemblies will be developed and presented at the project concept review. These will then be evaluated in performance testing and the results and recommendations presented at the project design review. Following the design review, documentation will be completed, vendors will be qualified where appropriate and shaft components and assembly processes will be qualified where appropriate. The final project review will then end the project.

The intermediate term project overview is presented in the following flow diagram.

**LOW PROFILE SHAFT**  
Intermediate Term Project Flow  
1/24/94

**Core Shaft Technologies**



## Description of Project Technologies

### Shaft Materials and Components Development

#### 1. Proximal Shafts - high stiffness, high strength polymers and composites

- a) PEEK tubing
- b) Polyester tubing
- c) Polyimide tubing
- d) Wire and/or ribbon reinforced polymers (polyimide, polyester)
- e) Liquid Crystal Polymer (LCP) tubing
- f) Stiffened polymer tubing with Ion Impregnation techniques

\* Proximal Shaft Applications: proximal RX shaft; proximal coaxial OTW outer shaft; proximal coaxial OTW inner member; proximal OTW elliptical shaft

#### 2. Distal Shafts - low stiffness, adequate strength polymer structures

- a) formulated polyethylenes
  - with lubricants for improved lubricity
  - with crosslinking agents to minimize degradation from irradiation and retain strength
  - with stabilizers to improve process control
- b) other polymers

\* Distal Shaft Applications: intermediate inner member for coaxial shafts; intermediate outer shaft for coaxial shafts; distal 25 cm for elliptical shafts; distal soft tip

### Shaft Structural Analysis and Design

This technology utilizes shaft material and component testing, "hand calculations" of shaft stiffness properties and computer modeling and structural analysis. These techniques are used to conduct:

1. Shaft component analysis
2. Shaft transitions analysis
3. Inflation/Deflation analysis
4. Shaft assembly analysis
5. Shaft assembly design
6. Shaft failure analysis

These methods will be used for both short term and intermediate term project objectives. Contributions to current high priority dilatation catheter development projects are being made by application of shaft assembly and transitions analysis and shaft failure analysis.

### Shaft Assembly Process Development

The intermediate term objective of developing optimized elliptical and coaxial shaft assemblies includes shaft assembly process optimization with the objective of improved assembly COPS and improved performance resulting from better shaft transitions. This technology will include:

1. Alternative welding/fusing methods for balloon/shaft and shaft component assembly.
  - a) polychromatic welding,
  - b) laser bonding
  - c) metalization of subcomponents for inductive/conductive welding
  - d) other methods
2. Application of vision technology to enhance process development and/or assist operator assembly in production.

### Basis for Technology Evaluation

The short term objectives of the Low Profile Shaft project, deliverables for high priority dilatation catheter projects, will be measured as part of those projects.

The intermediate term objectives of this project will be evaluated with the use of catheter shaft assemblies as vehicles to conduct catheter performance tests. The technology will be evaluated by:

<u>Attribute</u>	<u>Test</u>	<u>Criteria for Acceptance</u>
Catheter Performance	CPT, Heart Model, Animal Tests	push, track, wire movement, cross (shaft related) better or equal to leading front line catheters
	Heart Model, Animal Test	shaft does not kink during normal use
	Bench Tests, Heart Model, Animal Test	deflation time less than or equal to 12 seconds
Downsizing Systems	Heart Model	equal or improved use of 2 catheters in an 8F guide over leading front line catheters
	Heart Model	equal or improved utility in 6F guide over leading front line catheters
	Heart Model	equal or improved utility when catheter and 2 wires are used in a 7F guide over leading front line catheters
Improved Costs	Animal Test	equal or improved visualization over leading front line catheters
	COPS	lower COPS than .014 platform products

## **MANUFACTURING**

### **Capabilities of Processes**

The processes used to fabricate the new shaft components are either performed at vendors or within ACS. In-house processes all utilize existing extrusion technology, but with new polymer resins and additives. Process capabilities with these new materials are not yet determined. Vendor process capabilities are also undetermined at this time, however prototypes received from these vendors and discussions with them suggest that their processes are well understood and in control.

New catheter shaft assembly processes and their capabilities are not yet determined.

Process capabilities will be determined for all relevant processes during the concept development phase of this project and will be described at the Concept Review.

### **Safety Concerns**

There are no unusual safety concerns at this time associated with the processes or materials anticipated to be used for this project.

### **Equipment Requirements**

Equipment requirements for the Low Profile Shaft project have not yet been determined. New mixing and feeding equipment is being evaluated for the compounding extruder to support the formulations part of the project. New equipment is likely to be needed to enable new shaft assembly methods to be developed and used. Equipment requirements will be defined during the Concept Development phase of the project and will be presented at the Concept Review.

### **Suppliers**

1. Hudson International, Trenton Georgia - polyimide and polyimide composite tubing
  - a) currently on ACS vendor list
2. Acutech Plastics, Reading, PA - PEEK extrusions
  - a) confidentiality agreement in place
3. Superex Corp., Waltham, MA - liquid crystal polymer extrusions
  - a) agreements initiated but not yet in place
4. Spire Corp., Bedford, MA - ion impregnation services
  - a) agreements initiated but not yet in place

### **Equipment Facilities**

Additional or unusual facilities are not anticipated as a result of this project.

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